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| 10/765,564 | 01/27/2004 | William Dubrul | GMI 1001-5 | 8126 |

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| EXAMINER |
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ADAMS, AMANDA S

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| ART UNIT | PAPER NUMBER |
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3731

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/26/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/765,564 | Applicant(s) DUBRUL ET AL. | |
| | Examiner Amanda Adams | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/6/06, 8/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 8 is objected to because of the following informalities: "on said the capture element" is incorrect grammar. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1-6, 8-12, 14, 15, 17-19, 21, 22, and 24** are rejected under 35 U.S.C. 102(e) as being anticipated by Daniel et al (US 6,001,118).
3. **Regarding claims 1 and 10**, Daniel discloses the invention substantially as claimed including a catheter having a distal end, a multi-wing blood flow blocking element positioned near the distal end of the catheter, said multi-wing blood flow blocking element having a radially compressed insertion state and a radially expanded blocking state (figs. 7 and 8), an actuator associated with said catheter to move said blood flow blocking element from said compressed state to said expanded state (inflation tube is actuator in this embodiment), and said blood flow blocking element in said radially expanded blocking state having a generally funnel surface extending out

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from said distal end of said catheter (fig. 8). Alternative embodiments also meet the limitations as disclosed above (see fig. 6). The longitudinal elements of the malecot portion of the device are considered to be wings, as described in Figure 4 and Paragraph 29 in the specification of the instant application.

4. **Regarding claims 2 and 11**, Daniel further discloses an annular membrane (fig. 6, [47]) around the wings (fig. 6, [46]) of the blood flow blocking element.

5. **Regarding claims 3 and 12**, Daniel further discloses that the multiwing blood flow blocking element is a malecot device (fig. 14C; fig. 13B- with annular membrane [130]).

6. **Regarding claims 5, 14, 21, and 24**, Daniel discloses that the actuator extends, through said lumen, distal of said blood flow blocking element and when moved in a proximal direction, engages said blood flow blocking element to switch said blood flow blocking element from said retracted insertion state into said radially expanded blocking state (figs. 13A and 13B).

7. **Regarding claims 19 and 22**, Daniel discloses the invention substantially as claimed above, further disclosing an annular membrane around the structural members of the blood flow blocking element (fig. 6).

8. **Regarding claim 6**, Daniel discloses the method substantially as claimed, including inserting a catheter into a body passageway, said catheter having a multi-wing blood flow blocking element, providing said blood flow blocking element in a radially compressed state during said step of inserting, radially expanding said blood flow blocking element into a radially expanded state extending to or near to the wall of the

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body passageway after said step of inserting, said step of radially expanding including providing said expanded state with a generally funnel surface extending out from said distal end of said catheter, and using said expanded state of said blood flow blocking element for blocking passage of material around the outside of said catheter (figs. 7 and 8).

9. **Regarding claims 8 and 9**, Daniel discloses the method substantially as claimed including inserting an elongate tubular member, having a lumen, a proximal end and a distal end, into a body, providing a malecot-style tissue capture element in a radially compressed state during the step of inserting, radially expanding the tissue capture element into a radially expanded state after the step of inserting, and providing a proximal surface on said the capture element, the proximal surface extending out from the distal end of the elongate tubular member wherein the tissue is captured along the proximal surface (figs. 13A and 13B); and wherein the tissue capture element is generally funnel shaped when in the radially expanded state ([130]). Daniel also discloses additional embodiments that meet all of the above limitations (fig. 14C; fig. 8).

10. **Regarding claim 15**, Daniel discloses the method substantially as claimed above with respect to 8 and 9, further disclosing an axially movable actuator operably coupleable to the blood flow blocking element, wherein the actuator is moved to radially expand the bloodflow blocking element (figs. 13A and 13B).

11. **Regarding claims 17 and 18**, Daniel discloses the method substantially as claimed including above with respect to claims 8 and 9, further disclosing that the actuator is operably coupleable to the tissue capture element, wherein the actuator is

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moved to radially expand the tissue capture element into a radially expanded stent after the step of inserting (figs. 13A and 13B).

12. **Claims 25-27** are rejected under 35 U.S.C. 102(e) as being anticipated by Boyd et al (US 5,738,652).

13. Boyd discloses the method substantially as claimed including the steps of inserting a catheter into a body passageway, said catheter having a blood flow blocking element comprising structural members which define openings therebetween, the blood flow blocking element covered with an annular elastomeric, impermeable membrane, and an axially movable actuator operably coupleable to a distal portion of the blood flow blocking element, providing said blood flow blocking element in a radially compressed state during said step of inserting, and moving the actuator thereby radially expanding said blood flow blocking element into a radially expanded state extending to or near to the wall of the body passageway after said step of inserting, and using said expanded state of said blood flow blocking element for blocking passage of material around the outside of said catheter (col. 9, lines 56-65).

14. **Regarding claim 26**, Boyd discloses that the radial expansion includes providing an expanded state with a generally funnel surface extending out from the distal end of the catheter. The portion of the blood flow blocking element that is closest to the distal end of the catheter to extend away from the catheter in a funnel-like shape, at least in the region immediately closest to the catheter. (fig. 13).

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15. **Regarding claim 27**, Boyd discloses that the actuator-moving step comprises proximally moving the actuator (col. 9, lines 56-65).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. **Claims 4, 7, 13, 16, 20, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al (US 6,001,118) in view of Grayhack et al (US 4,611,594).

18. Daniel discloses the invention substantially as claimed above but fails to disclose an annular elastomeric impermeable membrane. However, Grayhack teaches that it is old and well-known in the art to have a blood flow blocking device with an elastomeric impermeable annular membrane (col. 4, lines 45-60). This provides blockage of blood flow as well as embolic debris, so that the user of the device may perform a procedure in a blood vessel without having to insert an occluder separate from the filter. Therefore it would have been obvious to replace the porous membrane of Daniela with an impermeable membrane.

Conclusion

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19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,605,102; US 4,6560,466; and US 5,643,282.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA


GLENN K. DAWSON
PRIMARY EXAMINER